

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES***

Applicant: Patrick J. Sweeney
Title: SPINAL DISC PROSTHESIS SYSTEM
Appl. No.: 10/619,757
Filing Date: 7/15/2003
Examiner: Philogene, Pedro
Art Unit: 3733
Conf. No.: 7389

BRIEF ON APPEAL

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with a credit card payment via EFS-Web in the amount of \$255.00 covering the 37 C.F.R. § 41.20(b)(2) appeal fee for a small entity. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

REAL PARTY IN INTEREST

The real party in interest is Spinal Generations, LLC, the assignee of record.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or assignee which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

This is an appeal from the Office Action mailed May 24, 2007 and the Advisory Action mailed August 20, 2007, rejecting claims 1-3, 8-10, 13-16, and 27-41. Claims 1-3, 8-10, 13-16, and 27-41 have been twice rejected and are being appealed. Claims 11 and 12 have been withdrawn from consideration. Claims 4-7, 17-26 and 42 have been cancelled.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the May 24, 2007 rejection. Applicant filed a Reply After Final under 37 C.F.R. § 1.113 on July 20, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The spinal column is comprised of 26 interlocking vertebrae with a spinal disc positioned between each vertebrae. See Specification at page 1, lines 15-16. These discs provide shock absorption and facilitate bending of the spine. See Specification at page 1, lines 18-19. Because spinal discs are susceptible to numerous ailments that impair their ability to serve these functions, an artificial disc, including a stabilizing element, may be implanted to replace a natural disc. See Specification at page 1, line 23 to page 2, line 8. Two common types of stabilizing elements are disc prostheses and fusion prostheses. See Specification at page 9, lines 22-23. A disc prosthesis is configured to mimic the shock absorption and joint properties of a natural disc. See Specification at page 2, lines 9-11. A fusion prosthesis is used in a procedure intended to permanently immobilize the joint between the two vertebrae. See Specification at page 3, lines 11-14.

The stabilizing element may be only one component of an artificial disc prosthesis system. See Specification at page 9, lines 16-19. The artificial disc prosthesis system may also include a scaffold assembly that is configured to hold the stabilizing element in the proper position. See Specification at page 9, lines 17-18. However, because an artificial disc prosthesis system is often required to last for a long period of time post-implantation, failure or obsolescence may create the need for replacement or revision of the system's stabilizing element. See Specification at page 2, lines 16-20. Therefore, the scaffold assembly may also be configured so that a stabilizing element may be repaired or replaced without having to remove and reinstall the entire prosthesis system. See Specification at page 9, lines 26-29.

The present invention relates to an artificial disc prosthesis system, a method for revising a stabilizing element using the artificial disc prosthesis system, and a disc prosthesis that may be used in the artificial disc prosthesis system.

Independent claim 1 is directed to an artificial disc prosthesis system including a stabilizing element. See Specification at page 9, lines 21-25 and Figs. 6-10 (showing the stabilizing element as a disc prosthesis comprising at least elements 124-144). The artificial disc prosthesis system further includes a scaffold assembly, the scaffold assembly including a first base adapted to attach to a first vertebrae. See Specification at page 15, lines 23-24 and superior base 100 shown in Figs. 6-7. A second base is adapted to attach to a second vertebrae. See Specification at page 15, lines 25-26 and inferior base 150 shown in Figs. 6-7. At least one appendage is removably attached to the first or the second base. See Specification at page 11, lines 17-18, page 15, lines 29-30 and bumpers 116 shown in Figs. 6-9. The appendage is removably attached to the first or the second base such that the first base, the second base and the at least one appendage define a cage between the first and second vertebrae. See Specification page 15, line 30 to page 16, line 2. The stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly. See Specification at page 11, lines 13-15. The stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages. See Specification at page 5, lines 21-24.

Independent claim 27 is directed to an artificial disc prosthesis system including a stabilizing means for stabilizing two adjoining vertebrae in the absence of a vertebral disc. See Specification at page 9, lines 21-25 and Figs. 6-10 (showing the stabilizing element as a disc prosthesis comprising at least elements 124-144). The artificial disc prosthesis system further includes a retaining means for removably retaining the stabilizing means when the artificial disc prosthesis system is disposed between two vertebrae. See Specification at page 11, lines 12-22. The retaining means comprises a removably attached appendage. See Specification at page 11, lines 17-18, page 15, lines 29-30 and bumpers 116 shown in Figs. 6-9. The retaining means is capable of accommodating stabilizing means of a plurality of shapes and sizes. See Specification at page 10, lines 18-21.

Independent claim 30 is directed to an artificial disc prosthesis system including a stabilizing element. See Specification at page 9, lines 21-25 and Figs. 6-10 (showing the stabilizing element as a disc prosthesis comprising at least elements 124-144). The artificial disc prosthesis system further includes a scaffold assembly, the scaffold assembly including a first base adapted to attach to a first vertebrae. See Specification at page 15, lines 23-24 and superior base 100 shown in Figs. 6-7. The scaffold assembly includes a second base adapted to attach to a second vertebrae. See Specification at page 15, lines 25-26 and inferior base 150 shown in Figs. 6-7. The scaffold assembly further includes one or more appendages removably coupled to the scaffold assembly and extending into an intervertebral space. See Specification at page 11, lines 17-18, page 15, lines 29-30 and bumpers 116 shown in Figs. 6-9. The one or more appendages are removably coupled to the scaffold assembly such that the first base, the second base and the one or more appendages define a cage in the intervertebral space. See Specification page 15, line 30 to page 16, line 2. The stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly. See Specification at page 11, lines 13-15. The one or more appendages may be removed to provide an opening into or out of which the stabilizing element may be inserted or extracted. See Specification at page 5, lines 21-24.

Independent claim 33 is directed to an artificial disc prosthesis system including a stabilizing element. See Specification at page 9, lines 21-25 and Figs. 6-10 (showing the stabilizing element as a disc prosthesis comprising at least elements 124-144). The artificial

disc prosthesis system further includes a scaffold assembly, the scaffold assembly including a first base adapted to attach to a first vertebrae. See Specification at page 15, lines 23-24 and superior base 100 shown in Figs. 6-7. The scaffold assembly includes a second base adapted to attach to a second vertebrae. See Specification at page 15, lines 25-26 and inferior base 150 shown in Figs. 6-7. The scaffold assembly further includes at least two appendages removably coupled to the scaffold assembly and extending into an intervertebral space. See Specification at page 11, lines 17-18, page 15, lines 29-30 and bumpers 116 shown in Figs. 6-9. The at least two appendages are removably coupled to the scaffold assembly such that the first base, the second base and the at least two appendages define a cage in the intervertebral space. See Specification page 15, line 30 to page 16, line 2. The stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly wherein the stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages. See Specification at page 5, lines 21-24.

Independent claim 38 is directed to an artificial disc prosthesis system including a stabilizing element. See Specification at page 9, lines 21-25 and Figs. 6-10 (showing the stabilizing element as a disc prosthesis comprising at least elements 124-144). The artificial disc prosthesis system further includes a scaffold assembly. See Specification at page 15, lines 23-26 (scaffold assembly comprising at least inferior base 150 and superior base 100 shown in Figs. 6-7). The scaffold assembly is adapted to be attached to an endplate of at least one of two vertebrae that define an intervertebral space. See Specification at page 14, lines 9-11. The scaffold assembly includes at least one removably attached appendage to removably retain the stabilizing element in the intervertebral space. See Specification at page 11, lines 17-18, page 15, lines 29-30 and bumpers 116 shown in Figs. 6-9. The scaffold assembly is capable of accommodating stabilizing elements of a plurality of shapes and sizes. See Specification at page 10, lines 18-21. The stabilizing elements may be removed from the scaffold assembly through an opening created by removing at least one of the appendages. See Specification at page 5, lines 21-24.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-3, 8-10, 13-16, and 27-41 are unpatentable under 35 U.S.C. § 102(e) as anticipated by Fehling et al., U.S. Patent No. 6,770,094.

ARGUMENT

I. LEGAL STANDARDS

The claims have been rejected under 35 U.S.C. § 102(e), which states:

A person shall be entitled to a patent unless-

....
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language. . . .

35 U.S.C. § 102(e).

The legal standards for anticipation under 35 U.S.C. §102 are well-settled. To establish anticipation, there must be “identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference.” Glaverbel S.A. v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554, 33 U.S.P.Q.2d 1496, 1498 (Fed. Cir. 1995); see also Cont’l Can Co. v. Monsanto Co., 948 F.2d 1264, 1267, 20 U.S.P.Q.2d 1746, 1748 (Fed. Cir. 1991). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

II. REJECTION OF CLAIMS 1-3, 8-10, 13-16 AND 27-41

In the Final Office Action mailed May 24, 2007, the Examiner rejected claims 1-3, 8-10, 13-16, and 27-41 as anticipated by Fehling et al., U.S. Patent No. 6,770,094, stating in part:

With respect to claims 1, 27, 30, 33, 38, Fehling et al discloses a stabilizing element (16, 18, 20, 22) a scaffold assembly comprising a first base (10) and a second base (12) at least one appendage (24) removably attached to the first or the second base, such that the bases and the appendage forming a cage between the first and second vertebrae, wherein the stabilizing element (16, 18, 20, 22) is retained in the cage without being rigidly attached to the scaffold assembly, and wherein the stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages (24) a first plate (10) and a second plate (12); as set forth in column 2, lines 55-67, column 3, lines 1-48; and as best seen in FIGS. 1-4.

With respect to claims 2, 3, 8-10, 13, 14, 28, 29, 34, 35, Fehling et al discloses all the limitations, as set forth in column 2, lines 55-67, column 3, lines 1-48; and as best seen in FIGS. 1-4.

With respect to method claims 15, 16, 31, 32, 36, 37, 39-41, the method steps, as set forth would have been inherently carried out in the operation of the device, as set forth above.

Office Action at pages 2-3.

III. THE REJECTION OF INDEPENDENT CLAIMS 1, 27, 30, 33, AND 38 AND OF THE CORRESPONDING DEPENDENT CLAIMS IS IMPROPER BECAUSE THE CITED REFERENCE FAILS TO DISCLOSE AT LEAST ONE ELEMENT OF EACH OF THE REJECTED CLAIMS

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros., 814 F.2d at 631, 2 U.S.P.Q.2d at 1053. “The identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). As explained below, the Examiner’s

rejection of claims 1-3, 8-10, 13-16, and 27-41 is improper because Fehling et al. fails to disclose at least one element of each of the rejected claims.

Referring to the cited reference, Fehling et al. discloses “an intervertebral disc prosthesis.” See col. 2, line 55. The “intervertebral disc prosthesis” of Fehling et al. includes “an upper cranial disc 10” and “a lower caudal disc 12” each configured to be anchored to “the adjacent faces of the vertebrae elements, while the intervertebral disc prosthesis is inserted between two vertebrae.” See col. 2, lines 55-64. “Spring means,” shown as elements 16, 18, 20, and 22 in FIGS. 1-4 respectively, are positioned between “upper cranial disc 10” and “lower caudal disc 12.” See e.g., col. 2, lines 65-67. In addition, Fehling et al. discloses “a protective coating 24” shown “in the form of a thin-walled cylindrical sleeve.” See col. 4, lines 7-8. “Protective coating 24” appears to be a contiguous elastic cylindrical barrier that is “wound up on cranial disc 10 and caudal disc 12.” See col. 4, lines 7-10 and Figs. 1-4. “Protective coating 24” provides a seal designed to “prevent tissue from growing into the intervertebral disc prosthesis.” See col. 4, lines 1-2. Accordingly, Fehling et al. discloses an intervertebral disc prosthesis encapsulated in a protective coating, but it does not disclose the removability of any element of the intervertebral disc prosthesis. Specifically, Fehling et al. does not appear to disclose the removability of either the protective coating or the springs.

A. Independent Claims 1, 27, 30, 33, and 38

Each of independent claims 1, 27, 30, 33, and 38 includes one or more “appendages” that are “removably attached” or “removably coupled.” While Fehling et al. does teach an intervertebral disc prosthesis, it fails to identically disclose a spinal disc prosthesis system including one or more “removably attached” or “removably coupled” “appendages” as recited in independent claims 1, 27, 30, 33, and 38.

In addition, independent claims 1, 33, and 38 each recite that “the stabilizing element may be removed . . . through an opening created by removing at least one of the appendages.” Independent claim 30 recites that “one or more appendages may be removed to provide an opening into or out of which the stabilizing element may be inserted or extracted.” Independent claim 27 recites “a retaining means for removably retaining the stabilizing

means.” Fehling et al. fails to identically disclose a spinal disc prosthesis system wherein “the stabilizing element may be removed . . . through an opening” as in claims 1, 33, and 38. Fehling et al. also fails to identically disclose a spinal disc prosthesis system wherein “one or more appendages may be removed to provide an opening into or out of which the stabilizing element may be inserted or extracted” as recited in claim 30. In addition, Fehling et al. fails to identically disclose a spinal disc prosthesis system having an element for “removably retaining the stabilizing means” as recited in claim 27. In fact, Fehling et al. fails to disclose the removability of *any* element from the disc prosthesis for *any* purpose.

On page 2 of the Office Action, the Examiner asserts that Fehling et al. discloses that “the stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages (24) a first plate (10) and a second plate (12).” In support of this assertion, the Examiner refers to all of the figures shown in Fehling et al. as well as all but 12 lines of its detailed description. Office Action at page 2 (Examiner citing “column 2, lines 55-67, column 3, lines 1-48” and “FIGS. 1-4” to support the assertion quoted above). Appellant respectfully asserts that, as stated above, Fehling et al. fails to disclose at least one element of each independent claim 1, 27, 30, 33, or 38.

In particular, Fehling et al. does not disclose the removal of “protective coating 24” in order to remove the “spring means” from the space between discs 10 and 12. In fact, Fehling et al. teaches that the “protective coating 24” is “wound up on” and “sealed and mounted” on “the cranial disc 10 and the caudal disc 12” to create an impermeable barrier to “prevent tissue from growing into the intervertebral disc prosthesis.” See col. 4, lines 1-11. The removal of “protective coating 24” would likely inhibit it from acting to “prevent tissue from growing into the intervertebral disc prosthesis.” Fehling et al. discloses nothing about “protective coating 24” being removably attached, and Fehling et al. discloses nothing about removal of the “spring means.”

Appellant has recognized the need “to easily revise, update, upgrade or replace” the stabilizing element of a disc prosthesis system. See Specification at page 2, lines 16-22. Appellant’s solution to this need is to provide a disc prosthesis system that allows for the stabilizing element to be removed while leaving other components of the disc prosthesis

system in place. See Specification at page 3, lines 6-8. Fehling et al., on the other hand, discloses an intervertebral disc prosthesis designed to prevent failure of the “spring means.” Fehling et al. states that “the substantial idea of the invention is to manufacture the spring means of the intervertebral disc prosthesis using a memory-metal alloy” where the purpose of the memory-metal alloy is to prevent “fatigue break of the spring means.” See col. 1, lines 48-50 and 64-65. As such, Fehling et al. is aimed at preventing one of the occurrences that triggers the need to replace a stabilizing element in a vertebral prosthesis. Given this, it is not surprising that Fehling et al. fails to disclose a device configured to allow the stabilizing element to be removed.

In the Advisory Action mailed August 20, 2007, the Examiner maintained the rejections of claims 1-3, 8-10, 13-16, and 27-41 stating that “[a]s claimed by applicant the stabilizing element ‘may be’ removed from the cage. So, it does not have to be removed.” Advisory Action at page 2. Referring to Fehling et al., the Examiner continued “[o]ne can remove the stabilizing element by creating an opening in the protective coating and using a pair of pliers to pull the stabilizing element and insert a new one if one so desired.” Advisory Action at page 2. The Examiner fails to refer to any part of Fehling et al. or any other reference to support these contentions. As discussed above, Appellant respectfully asserts that Fehling et al. does not teach one or more “removably attached” or “removably coupled” “appendages.” Neither does Fehling et al. teach allowing access to and removal of a stabilizing element as required in independent claims 1, 27, 30, 33, and 38. In addition, Fehling et al. fails to disclose “creating an opening in the protective coating and using a pair of pliers to pull the stabilizing element and insert a new one if one so desired” as stated by the Examiner. As discussed above, creating a breach in the “protective coating 24” of Fehling et al. would likely prevent the “protective coating 24” from acting to “prevent tissue from growing into the intervertebral disc prosthesis.” Lastly, Fehling et al. discloses neither the need nor the method for removing a “spring means” from the intervertebral disc prosthesis device disclosed.

Providing a spinal disc prosthesis system that allows for post implantation removal of the system’s stabilizing element without having to remove the entire spinal disc prosthesis system is an advance over previous approaches that, like Fehling et al., attempt to provide

disc prostheses that resist failure. Because Fehling et al. does not identically disclose one or more elements in each of the claims, independent claims 1, 27, 30, 33, and 38 and corresponding dependent claims 2, 3, 8-10, 13-16, 28, 29, 31, 32, 34-37, and 39-41 are not anticipated under 35 U.S.C. § 102(e).

B. Independent Claim 33

In rejecting independent claim 33, the Examiner did not distinguish between independent claim 33 and the other independent claims. See Office Action at page 2. Appellant respectfully asserts that in addition to the reasons discussed above, Fehling et al. fails to disclose additional elements or limitations present in independent claim 33.

Independent claim 33 includes “a scaffold assembly comprising ... at least two appendages removably coupled to the scaffold assembly.” See Specification at page 15, lines 29-30 and Fig. 7 (disclosing at least 2 appendages, shown as “[b]uttresses, each having a bumper 116”). Fehling et al. does not identically disclose “at least two appendages removably coupled to the scaffold assembly.” The Examiner identifies the “protective coating 24” of Fehling et al. as an “appendage” as that term is used in Appellant’s claims. As discussed above, Fehling et al. does not disclose “protective coating 24” being removably coupled. Further, even if the “protective coating 24” of Fehling et al. is found to be a removably coupled appendage, Fehling et al. appears to disclose only a single “protective coating 24” not “at least two” as recited in independent claim 33. See col. 4, lines 1-11. While at first glance it may appear that the drawings of Fehling et al. each disclose two “protective coating[s] 24” shown as vertically positioned rectangles in the drawings, “protective coating 24” appears to be a single element in each drawing. See Figs. 1-4. Because the drawings of Fehling et al. appear to be cross-sectional views, they depict a single “thin-walled cylindrical” “protective coating 24” as the two vertically positioned rectangles labeled 24 in the drawings. See col. 4, 7-10 and Figs. 1-4. Accordingly, claim 33 is further patentable over Fehling et al.

IV. DEPENDENT CLAIMS 3, 8-10, 28, 29, 34, AND 35 ARE FURTHER PATENTABLE OVER THE CITED REFERENCE FOR REASONS IN ADDITION TO THOSE SET FORTH ABOVE

Regarding dependent claims 2, 3, 8-10, 13, 14, 28, 29, 34, and 35, the Examiner states “Fehling et al. discloses all the limitations, as set forth in column 2, lines 55-67, column 3, lines 1-48; and as best seen in FIGS. 1-4.” Office Action at page 3. Appellant respectfully asserts that, in addition to the reasons discussed above regarding the independent claims, Fehling et al. fails to disclose additional elements or limitations recited in dependent claims 3, 8-10, 28, 29, 34, and 35.

A. Dependent Claim 3

Dependent claim 3 further recites that “the stabilizing element is a fusion prosthesis.” A fusion prosthesis is a type of stabilizing element used to fuse together the vertebrae adjacent to a spinal disc prosthesis system during an arthrodesis procedure. See Specification at page 2, lines 22-24 and page 3, lines 10-14 and lines 19-20. Fehling et al. does not identically disclose a “fusion prosthesis” as recited in claim 3. Fehling et al. only discloses a disc prosthesis designed to provide “good mobility of the vertebrae” and “soft axial shock absorption.” See col. 1, lines 44-47 and col. 2, lines 21-24. Appellant respectfully asserts that Fehling et al. fails to disclose any element designed to fuse adjacent vertebrae thereby preventing motion between adjacent vertebrae. Accordingly, claim 3 is further patentable over Fehling et al.

B. Dependent Claims 8-10

Dependent claim 8 and claims 9 and 10, which depend from claim 8, further recite that “the scaffold assembly further comprises a first plate positioned above the stabilizing element and a second plate positioned below the stabilizing element, the second plate disposed opposite and in substantially parallel relation to the first plate, such that the stabilizing element is retained between the first and second plates.” See Specification at page 5, lines 27-30, page 15, lines 14-20 and Figs. 5a-5c (“the scaffold assembly may further include plates positioned within the intervertebral space above and below the disc prosthesis”). The “first

plate” and “second plate” are elements of dependent claims 8-10 in addition to the “first base” and “second base” recited in independent claim 1. Fehling et al. discloses an intervertebral disc prosthesis including “an upper cranial disc 10” and “a lower caudal disc 12” each configured to be anchored to “the adjacent faces of the vertebrae elements.” See col. 2, lines 55-64. Fehling et al. also discloses a “spring means,” shown as elements 16, 18, 20, and 22 in FIGS. 1-4, positioned between “upper cranial disc 10” and “lower caudal disc 12.” See e.g., col. 2, lines 65-67. Fehling et al. discloses no additional elements comparable to the “first plate” and the “second plates” of dependent claims 8-10. Accordingly, claims 8-10 are further patentable over Fehling et al.

C. Dependent Claim 9

Dependent claim 9 further recites that “the first plate and the second plate have high friction outer surfaces.” See Specification at page 6, lines 1-3 (“The surfaces of the plates which contact the disc prosthesis may be high friction surfaces, in which case the prosthesis is held more or less rigidly between the plates”). Fehling et al. does not identically disclose any component of the intervertebral disc prosthesis as having “high friction outer surfaces.” Accordingly, claim 9 is further patentable over Fehling et al.

D. Dependent Claim 10

Dependent claim 10 further recites that “the first plate and the second plate have low friction outer surfaces.” See Specification at page 6, lines 3-6 (“the surfaces of the plates which contact the disc prosthesis may be low friction surfaces, in which case the disc prosthesis may have some limited lateral range of motion between the plates”). Fehling et al. does not identically disclose any component of the intervertebral disc prosthesis as having “low friction outer surfaces.” Accordingly, claim 10 is further patentable over Fehling et al.

E. Dependent Claim 28

Claim 28, depending from claim 1, recites that “the scaffold assembly comprises at least two appendages attached to the first or the second base.” See Specification at page 15, lines 29-30 and Fig. 7 (disclosing at least 2 appendages, shown as “[b]uttresses, each having a

bumper 116”). Fehling et al. does not identically disclose “at least two appendages attached to the first or the second base.” The Examiner identifies the “protective coating 24” of Fehling et al. as an “appendage” as that term is used in claims 1 and 28. As discussed above, Fehling et al. does not disclose “protective coating 24” being removably attached. Further, even if the “protective coating 24” of Fehling et al. is found to be a removably attached appendage, Fehling et al. appears to disclose only a single “protective coating 24” not “at least two” as recited in dependent claim 28. See col. 4, lines 1-11. Accordingly, claim 28 is further patentable over Fehling et al.

F. Dependent Claim 29

Claim 29, depending from claim 1, recites that “the first and second bases are ring-shaped.” See Specification at page 14, lines 6-7 and Figs. 1a and 1b (“FIG. 1a shows a top view of a scaffold base 100 composed of a ring 102 which defines a central opening 104”). Appellant defines a structure as ring-shaped when “it has a peripheral section which defines a central opening.” See Specification at page 4, lines 19-20. Fehling et al. does not identically disclose either “cranial disc 10” or “caudal disc 12” as being “ring-shaped.” Fehling et al. only states that “the cross-section of the discs 10 and 12 substantially corresponds to the form of the natural intervertebral disc and vertebra element.” See col. 2, lines 58-61. Accordingly, claim 29 is further patentable over Fehling et al.

G. Dependent Claim 34

Dependent claim 34 recites that “the appendages comprise at least one buttress attached to each of the first and second bases.” Appellant states that buttresses include “bumpers 116” that “extend upwardly or downwardly beyond bases 100 and 150 to form a cage in which the disc prosthesis is removably housed.” See Specification at page 15, line 29 to page 16, line 2; see also Specification at page 14, lines 16-29 and Figs. 2 and 7. Fehling et al. does not identically disclose “a buttress” as recited in dependent claim 34. As discussed above, Fehling et al. only appears to disclose “an upper cranial disc 10,” “a lower caudal disc 12,” “spring means,” and “protective coating 24.” None of these elements is a “buttress” as claimed by Appellant. Accordingly, claim 34 is further patentable over Fehling et al.

H. Dependent Claim 35

Dependent claim 35 recites that “the buttresses may be attached to the first or second bases at different positions or alignments.” See Specification at page 5, lines 16-19 (“The base of the scaffold assembly may be designed such that buttresses may be adjustably attached to the base at different positions and alignments depending on the size and shape of the stabilizing element”). As discussed above, Fehling et al. does not identically disclose “a buttress” as recited in dependent claim 35. Further, Fehling et al. does not identically disclose the buttress being attached “at different positions or alignments.” Because Fehling et al. fails to disclose “a buttress,” it can hardly contain a disclosure regarding the position and alignment of the attachment of “the buttress” “to the first or second bases” as recited in claim 35. Accordingly, claim 35 is further patentable over Fehling et al.

V. DEPENDENT CLAIMS 15, 16, 31, 32, 36, 37, AND 39-41 ARE FURTHER PATENTABLE OVER THE CITED REFERENCE FOR REASONS IN ADDITION TO THOSE SET FORTH ABOVE

Regarding dependent method claims 15, 16, 31, 32, 36, 37, and 39-41, the Examiner states “the method steps, as set forth would have been inherently carried out in the operation of the device, as set forth above.” Office Action at page 3. Appellant respectfully asserts that in addition to the reasons discussed above regarding the independent claims, Fehling et al. fails to disclose additional elements or limitations recited in dependent method claims 15, 16, 31, 32, 36, 37, and 39-41.

A. Dependent Claims 15, 31, 36, and 39

Dependent claims 15, 31, and 36 each recite the steps of “removing a first stabilizing element from the cage” and “inserting a second stabilizing element into the cage.” Dependent claim 39 recites the steps of “removing a first stabilizing element from the scaffold assembly” and “inserting a second stabilizing element into the scaffold assembly.” See Specification at page 6, lines 21-24 (“a first stabilizing element which is removably retained in an intervertebral space by a scaffold assembly is replaced by a second stabilizing element without removing the scaffold assembly”). Applicant respectfully asserts that method steps

of claims 15, 31, 36, and 39 would not inherently be performed by use of the device of Fehling et al. In addition, Fehling et al. does not identically disclose the replacement of a stabilizing element.

As discussed above, Fehling et al. discloses an intervertebral disc prosthesis having “spring means” designed to resist failure and a “protective coating 24” designed to prevent tissue from growing into the prosthesis. The function of these elements in the device of Fehling et al. does not appear to permit replacement of a stabilizing element in an artificial disc prosthesis system. Consequently, the normal and usual operation of the device of Fehling et al. would not necessarily perform the steps of “removing a first stabilizing element from the cage” and “inserting a second stabilizing element into the cage” as recited in claims 15, 31, and 36 or of “removing a first stabilizing element from the scaffold assembly” and “inserting a second stabilizing element into the scaffold assembly” as recited in claim 39. Nowhere does Fehling et al. disclose removal of a first stabilizing element and insertion of a second stabilizing element into a disc prosthesis system as recited in dependent method claims 15, 31, 36, and 39. Accordingly, claims 15, 31, 36, and 39 and claims 16, 32, 37, 40, and 41, which depend from claims 15, 31, 36, and 39, respectively, are further patentable over Fehling et al.

B. Dependent Claims 16, 32, 37, and 40

Dependent claims 16, 32, 37, and 40, which depend from claims 15, 31, 36, and 39 respectively, each recite that “the first stabilizing element is a disc prosthesis and the second stabilizing element is a fusion prosthesis.” See Specification at page 6, lines 26-27. As discussed above, a fusion prosthesis is a type of stabilizing element used fuse the vertebrae adjacent to the spinal disc prosthesis system during an arthrodesis procedure. See Specification at page 2, lines 22-24 and page 3, lines 10-14 and lines 19-20. Fehling et al. only discloses a disc prosthesis designed to provide “good mobility of the vertebrae” and “soft axial shock absorption.” See col. 1, lines 44-47 and col. 2, lines 21-24. Appellant respectfully asserts that Fehling et al. fails to disclose replacement of a disc prosthesis with any element designed to fuse adjacent vertebrae thereby preventing motion between adjacent vertebrae. Accordingly, claims 16, 32, 37, and 40 are further patentable over Fehling et al.

C. Dependent Claim 41

Dependent claim 41, which depends from claim 39, recites that “the first stabilizing element can be removed by an anterior or a lateral approach and the second stabilizing element can be inserted by an anterior or a lateral approach.” See Specification at page 10, lines 15-17. In addition to failing disclose removal and replacement of a stabilizing element, Fehling et al. also fails disclose the specific approach that would be taken in carrying out such removal and replacement. Accordingly, claim 41 is further patentable over Fehling et al.

VI. CONCLUSION

In view of the foregoing, Appellant submits that claims 1-3, 8-10, 13-16, and 27-41 are not properly rejected as being anticipated under 35 U.S.C. § 102(e). Accordingly, Appellant respectfully requests that the Board reverse the claim rejections and order that a Notice of Allowance respecting all pending claims be issued.

Respectfully submitted,

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CLAIMS APPENDIX

1. An artificial disc prosthesis system comprising:
 - (a) a stabilizing element; and
 - (b) a scaffold assembly comprising:
 - (i) a first base adapted to attach to a first vertebrae;
 - (ii) a second base adapted to attach to a second vertebrae; and
 - (iii) at least one appendage removably attached to the first or the second base, such that the first base, the second base and the at least one appendage define a cage between the first and second vertebrae; wherein the stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly, and wherein the stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages.
2. The artificial disc prosthesis system of claim 1, wherein the stabilizing element is a disc prosthesis.
3. The artificial disc prosthesis system of claim 1, wherein the stabilizing element is a fusion prosthesis.
8. The artificial disc prosthesis system of claim 1, wherein the scaffold assembly further comprises a first plate positioned above the stabilizing element and a second plate positioned below the stabilizing element, the second plate disposed opposite and in substantially parallel relation to the first plate, such that the stabilizing element is retained between the first and second plates.

9. The artificial disc prosthesis system of claim 8, wherein the first plate and the second plate have high friction outer surfaces.

10. The artificial disc prosthesis system of claim 8, wherein the first plate and the second plate have low friction outer surfaces.

13. The artificial disc prosthesis system of claim 1, wherein the scaffold assembly comprises a material selected from metal, ceramic and plastic.

14. The artificial disc prosthesis system of claim 1, wherein the scaffold assembly comprises a material selected from cobalt chrome or titanium.

15. A method for revising a stabilizing element in the artificial disc prosthesis system of claim 1, the method comprising:

- (a) removing a first stabilizing element from the cage; and
- (b) inserting a second stabilizing element into the cage.

16. The method of claim 15, wherein the first stabilizing element is a disc prosthesis and the second stabilizing element is a fusion prosthesis.

27. An artificial disc prosthesis system comprising:

- (a) a stabilizing means for stabilizing two adjoining vertebrae in the absence of a vertebral disc; and
- (b) a retaining means for removably retaining the stabilizing means when the artificial disc prosthesis system is disposed between two vertebrae, wherein the retaining means comprises a removably attached appendage and is capable of accommodating stabilizing means of a plurality of shapes and sizes.

28. The artificial disc prosthesis of claim 1, wherein the scaffold assembly comprises at least two appendages attached to the first or the second base.

29. The artificial disc prosthesis system of claim 1, wherein the first and second bases are ring-shaped.

30. An artificial disc prosthesis system comprising:

- (a) a stabilizing element; and
- (b) a scaffold assembly comprising:
 - (i) a first base adapted to attach to a first vertebrae;
 - (ii) a second base adapted to attach to a second vertebra; and
 - (iii) one or more appendages removably coupled to the scaffold assembly and extending into an intervertebral space, such that the first base, the second base and the one or more appendages define a cage in the intervertebral space;

wherein the stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly and further wherein the one or more appendages may be removed to provide an opening into or out of which the stabilizing element may be inserted or extracted.

31. A method for revising a stabilizing element in the artificial disc prosthesis system of claim 30, the method comprising:

- (a) removing a first stabilizing element from the cage; and
- (b) inserting a second stabilizing element into the cage.

32. The method of claim 31, wherein the first stabilizing element is a disc prosthesis and the second stabilizing element is a fusion prosthesis.

33. An artificial disc prosthesis system comprising:

- (a) a stabilizing element; and
- (b) a scaffold assembly comprising:
 - (i) a first base adapted to attach to a first vertebra;
 - (ii) a second base adapted to attach to a second vertebra; and
 - (iii) at least two appendages removably coupled to the scaffold

assembly and extending into an intervertebral space, such that the first base, the second base and the at least two appendages define a cage in the intervertebral space;

wherein the stabilizing element is retained in the cage without being rigidly attached to the scaffold assembly and wherein the stabilizing element may be removed from the cage through an opening created by removing at least one of the appendages.

34. The artificial disc prosthesis system of claim 33, wherein the appendages comprise at least one buttress attached to each of the first and second bases.

35. The artificial disc prosthesis system of claim 33, wherein the buttresses may be attached to the first or second bases at different positions or alignments.

36. A method for revising a stabilizing element in the artificial disc prosthesis system of claim 33, the method comprising:

- (a) removing a first stabilizing element from the cage; and
- (b) inserting a second stabilizing element into the cage.

37. The method of claim 36, wherein the first stabilizing element is a disc prosthesis and the second stabilizing element is a fusion prosthesis.

38. An artificial disc prosthesis system comprising:

- (a) a stabilizing element; and
- (b) a scaffold assembly adapted to be attached to an endplate of at least one of two vertebrae that define an intervertebral space and comprising at least one removably attached appendage to removably retain the stabilizing element in the intervertebral space; wherein the scaffold assembly is capable of accommodating stabilizing elements of a plurality of shapes and sizes, and wherein the stabilizing elements may be removed from the scaffold assembly through an opening created by removing at least one of the appendages.

39. A method for revising a stabilizing element in the artificial disc prosthesis system of claim 38, the method comprising:

- (a) removing a first stabilizing element from the scaffold assembly; and
- (b) inserting a second stabilizing element into the scaffold assembly.

40. The method of claim 39, wherein the first stabilizing element is a disc prosthesis and the second stabilizing element is a fusion prosthesis.

41. The method of claim 39, wherein the first stabilizing element can be removed by an anterior or a lateral approach and the second stabilizing element can be inserted by an anterior or a lateral approach.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.